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16/139
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Ref:
MLX342proposaltoenableukpharmacistsdispe

Dear Mr Drepaul

**Re RPSGB Response to proposals to amend Section 58 of the Medicines Act 1968 to enable UK pharmacists to dispense prescription only medicines prescribed by doctors and dentists registered in EU member states and Switzerland.**

I write on behalf of the Royal Pharmaceutical Society of Great Britain (RPSGB) in response to the proposals in the above consultation.

The RPSGB is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, a role that is expected to become statutory under new legislation soon.

The primary objectives of the RPSGB are to lead, regulate, develop and represent the profession of pharmacy.

Please do not hesitate to contact me if you have any questions about the issues raised in this response.

Yours sincerely

Priya Sejpal
Acting Head of Professional Ethics

**RPSGB Response to Proposals to amend Section 58 of the Medicines Act 1968 to enable UK pharmacists to dispense prescription only medicines prescribed by doctors and dentists registered in EU member states and Switzerland.**

The Royal Pharmaceutical Society of Great Britain (RPSGB) is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, a role that is expected to become statutory under new legislation soon. The primary objectives of the RPSGB are to lead, regulate, develop and represent the profession of pharmacy.

The RPSGB recognises the importance of access to medicines for those EEA citizens who visit the UK. The RPSGB welcomes the proposals to ensure that continuity of care is maintained. However, we do have a number of concerns about the implications of the proposed change to current legislation. The RPSGB wishes to ensure that patient safety is not compromised, that pharmacists can continue to be satisfied of the clinical appropriateness of medicines supplied to individual patients and continue to exercise their professional judgement in the best interests of the patient.

The first principle of the RPSGB Code of Ethics for pharmacists and pharmacy technicians is 'Make the care of patients your first concern'. In meeting the principle, the Code states that pharmacists and pharmacy technicians must 'seek to ensure safe and timely access to medicines and take steps to be satisfied of the clinical appropriateness of medicines supplied to individual patients.'

If the proposals as outlined in the consultation document are implemented, UK pharmacists will face a number of practical problems in meeting their legal and professional requirements. The RPSGB welcomes the view that these changes will be enabling rather than mandatory and that UK pharmacists will not be compelled to dispense a prescription written in another Member State by a non-UK registered practitioner if they do not judge it safe to do so. However, in order for pharmacists to exercise proper judgement and make an informed decision about whether or not it is safe and appropriate to make a supply, a number of potential difficulties will need to be overcome.

In particular, UK pharmacists could face serious obstacles in attempting to verify the authenticity of a prescriber who is not known to them. To verify an EEA prescriber's status, UK pharmacists will require access to overseas doctors and dentists registers to check their registration and confirm that there are no restrictions placed upon them. UK pharmacists are also likely to encounter language barriers that may prevent them from carrying out such a registration check. Attempts to verify the authenticity of the prescriber will be further hampered by the fact that most other EEA states have registration systems which are at variance with our own. In addition pharmacists are not going to be aware of the appropriate authority to approach to verify registration status. It is the RPSGB understanding that very few EEA competent authorities have real-time web-based publicly searchable lists of registered practitioners.

Further language barriers may be encountered when assessing the content of the prescription, for example, as a result of differences in drug names, abbreviations, dosages and directions. A pharmacist who needs to contact the prescriber to clarify any of these differences is likely to encounter additional language barriers, both in trying to contact the prescriber and also in communicating any queries they may have. If these difficulties are not overcome, patient safety could be placed at risk. The pharmacist could be placed in a professionally compromising position of a patient requiring vital medicines and a regulatory minefield to navigate, in order to verify authenticity.

The RPSGB has a duty to enforce the provisions of section 58 of the Medicines Act 1968 and we have concerns that the proposed changes could present a number of difficulties in ensuring

appropriate and adequate enforcement. It is anticipated that due to the resource implications of such changes, the RPSGB Inspectorate will only be in a position to deal with problems as they arise rather than routinely checking the authenticity of these prescriptions.

The RPSGB has the following views on the issues raised in the consultation letter.

**Proposed Future-Proofing**
The RPSGB recognises the importance of future proofing legislation to take account of non-medical practitioners who may gain prescribing rights in EEA member states in the future; however, we do have some concerns about the potential implications of this. Currently only the UK has legislative provision for independent prescribing by non-medical prescribers, such as nurses and pharmacists. Therefore, competencies for these extended roles are not addressed in the pan-European education and training requirements. The RPSGB would also question how pharmacists will reasonably be expected to know which groups of healthcare professionals have been awarded prescribing rights in their respective EU country and what limitations may be placed on their ability to prescribe. In addition there is no pan-European agreed Code of Practice or Ethics to underpin patient safety and risk management in this field.

Furthermore, the RPSGB would not wish to see UK pharmacists in the position where they can accept prescriptions from practitioners from other EU member states, but UK equivalents are not permitted to issue prescriptions for dispensing across Europe.

**Controlled Drugs**
The RPSGB supports the proposal to exclude CDs, Schedule 1-5, from the provisions. Due to the nature of Controlled Drugs, the RPSGB believes that the exclusion of all Schedules of CD will best serve public interest and patient safety.

The potential for Schedule 5 CDs to be included should only be explored when the necessary safeguards are in place. The RPSGB would support later implementation in respect of CDs when there has been a chance to evaluate the impact of these changes. Patient safety must be at the forefront of these considerations. If in the future, changes were to be made to enable the dispensing of Schedule 5 CDs, changes would also need to be made to Controlled Drugs (Supervision of Management and Use) Regulations 2006, as there would be implications on the role of Accountable Officers.

**Drugs that do not have a valid Marketing Authorisation in the UK**
For reasons of patient safety, the RPSGB does not believe that UK pharmacists should dispense prescriptions from doctors or dentists registered in EU member states and Switzerland where the medicine does not have a valid UK Marketing Authorisation. The RPSGB currently advises pharmacists that:

*If a product without a marketing authorisation is supplied or a product supplied outside its marketing authorisation indications and an adverse reaction is suffered to it, the supplying pharmacist may assume some liability with the doctor who prescribed it.*

*The extent of this liability depends on the facts of every case. The law expects a pharmacist take the steps that a reasonably competent pharmacist would take judged in accordance the accepted standards of his profession regardless of his or her relative experience. The pharmacist must ensure that the supply is made in the best interests of the patient and the potential risk to the patient of making the supply has to be weighed against the detriment to the patient of not making the supply.*

*Reasonable steps should be taken to ensure that the prescribing doctor knew that he was using a product outside its marketing authorisation and what the possible consequences that might be. Pharmacists should liaise with the prescriber and in the light of the available data make a decision*

*as to whether or not to make a supply. Data on the use of the product for the particular indication may be available from the manufacturer, drug information services and possibly the Information Pharmacists, Information Centre at the Royal Pharmaceutical Society. It may be that the prescriber has had substantial experience of using this product in this way.*

With this in mind, it is unlikely that UK pharmacists will be able to fulfil the above requirements. Again this will be largely due to the difficulty in contacting the prescriber and overcoming language barriers with both the prescriber and patient and as result patient safety could be compromised. The collaborative approach envisaged in this current guidance would be difficult to achieve across jurisdictional barriers.

**Form of Prescribing**
The RPSGB does not agree with the proposal that a prescription issued by a doctor or dentist in another EU member state or Switzerland does not have to satisfy the conditions specified in Article 15 of the Prescription Only Medicines (Human Use) Order 1997 . The RPSGB recognises that to inform all prescribers in Member States and Switzerland of the UK's legislation may not be effective, however without making explicit the minimum necessary fields of data required on a prescription, a UK pharmacist will potentially not have sufficient information to dispense the medicine, or be satisfied of the prescriptions authenticity. In addition, ensuring lawful and clinically appropriate supplies of medicines against these prescriptions will be difficult.

The RPSGB is concerned that this proposal will mean that prescriptions issued by prescribers in all Members States and Switzerland will be subject to lower controls than those placed on UK prescribers. When considering patient safety, the RPSGB cannot find justification in enabling doctors or dentists from EU Member States or Switzerland to write prescriptions that contain less than the current requirements in the UK. This would be contrary to the wider public interest.

Furthermore, should the proposals outlined in the consultation be accepted, it raises the question of whether UK pharmacists will be allowed to dispense prescriptions issued by UK prescribers that do not comply with Medicines Act legislation.

Such changes will raise a number of difficulties regarding enforcement of Section 58 of the Medicines Act and compliance with the Code of Ethics.

As a minimum the RPSGB believes that the following information must be present on a prescription:

1. Name and Address of the prescriber
2. Name and Address of the patient, and age if under 12.
3. Name, form and strength of the medicinal product
4. Dosage instructions
5. Date of issue
6. Signature

**Exemption in cases involving another's default**
The RPSGB agrees that in line with existing provisions, the restrictions imposed by section 58(2)(a) should not apply to the sale or supply of a POM by a person, who having exercised all due diligence, believes on reasonable grounds that the product sold is not a POM.

**Exemption in the case of a forged prescription**
The RPSGB agrees that a due diligence clause is necessary for prescriptions which are presented as being, but are not, from an EEA doctor or dentist. Pharmacists face many difficulties in detecting forged prescriptions. In many instances, the forger may make a fundamental error in writing the prescription which can often alert the pharmacist to a possible forgery. However, the RPSGB is concerned that the potential changes outlined within this consultation, particularly the proposed relaxations of prescription requirements, will make it more

difficult for pharmacists to detect errors in prescriptions and consequently may result in an increase in the likelihood of a forged prescription being dispensed. Pharmacists are not specialists in the detection of crime and should not be found in breach of the Medicines Act for supply against forged prescriptions which they had reasonable grounds to believe is genuine.

**Professional Guidance**
As the professional body for pharmacists, the RPSGB could issue guidance to its registrants in relation to the dispensing of prescriptions issued by EEA prescribers. The RPSGB current advice on this matter can be seen in *Appendix A.* The RPSGB believes that the following are areas which would require further clarification in professional guidance:

- Contact details of registration bodies across the jurisdiction.
- The form of the prescription (The RPSGB believes that the minimum fields necessary should be a statutory requirement, however in the event that this is not agreed, the form of the prescription can be outlined in professional guidance).
- Other checks to make. For example, the identity of the patient.
- Record keeping.
- Emergency supplies.

The RPSGB believes the MHRA should facilitate registration checks for doctors and dentists registered in the EU member states and Switzerland.

**Impact of Legislation on Business**
In general, these changes are unlikely to impact on the everyday practice of many community pharmacists. However, there are pharmacies, such as those based within or near airports, ports and international train stations where these changes may have significant impact as it is more likely that a prescription of this nature may be presented.

**Other Areas of Concern**
The consultation does not make reference to emergency supplies at the request of either a prescriber from an EEA member state or a patient. The RPSGB would request clarification in this area. Should doctors and dentists registered in EEA member states or Switzerland fall within the definition of an ‘appropriate practitioner’ guidance will be required in relation to emergency supplies. The RPSGB does not consider it appropriate for the emergency supply provisions to apply. However, if the proposal in this consultation enables emergency supplies to be made, the RPSGB would seek that current Medicines Act requirements should apply. There may also be a need to consider whether other drugs which have the potential for misuse should be excluded from these provisions.

The RPSGB would welcome further details of how the impact of these changes will be evaluated and as a result of that evaluation how any necessary safeguards will be introduced. Patient safety is a critically important factor in considering this issue and not just the safety of patients within the jurisdiction of the RPSGB, but patient safety across jurisdictional boundaries.

Miss Priya Sejpal
Acting Head of Professional Ethics

**Appendix A**

In the United Kingdom, under the Medicines Act 1968, as amended, a prescription has to be written by an appropriate practitioner. United Kingdom registered doctors and dentists are appropriate practitioners for all prescription only medicines (POM). Therefore a doctor registered elsewhere would not be an appropriate practitioner for the purposes of the Medicines Act 1968, as amended, unless s/he had dual registration with the General Medical Council.

The current position of the UK Government is that where a pharmacist in the UK is presented with a prescription written by a prescriber from a EU Member State, that this should only be dispensed where the prescriber is also registered with the General Medical Council in the UK.

This UK policy applies only to POMs and such medicines can be supplied against prescriptions issued by prescribers established in another Member State who are also registered in the UK. In addition, EU residents may still seek the services of UK registered prescribers and can therefore obtain a prescription written by such a prescriber and have it dispensed in the UK.

Pharmacists must be able to check the registration status of prescribers to allow them to confirm the authenticity of the prescription which may help to prevent fraudulent supplies against fake prescriptions and would also allow queries to be clarified with the prescriber. Should the prescription be written by an EU prescriber, these checks would be more difficult to make.

The view taken by the European Commission is that the UK Government's position in relation to the dispensing of EU prescriptions amounts to a restriction of the fundamental freedom to provide services, both with regard to patients and prescribers. The EU has recently challenged the UK Government's position and as a result the Government is currently undertaking a consultation, (MLX 342), which can be viewed on the Medicines and Healthcare products Regulatory Agency's (MHRA's) website at: <http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&useSecondary=true&ssDocName=CON2032065&ssTargetNodeId=373>. Hence, the position is currently far from clear. Hopefully, the results of the consultation will help clarify the situation.

Should a pharmacist decide to take the view of the European Commission, they would have to ensure that s/he has made all the necessary checks so that the pharmacist is satisfied that it is in the patient's best interests to supply and that the prescription is legally valid. The potential problems that the pharmacist would have to overcome would be:

- Access to overseas doctors registers to check registration in that country and that there are no restrictions placed upon them;
- Ability to contact and query prescriptions issued by EU prescribers;
- Difference in naming of drugs within EU countries;
- Language problems, problems with abbreviations and dosages;
- Reciprocal charging arrangements;
- Detection, forgery and enforcement;
- Stock problems resulting from differences in drug names;
- Differences in licensed indications of drugs in different EU countries;

It is important to note that the above position held by the European Commission only applies to the EU and not to prescribers registered outside the EU (for example, America or Canada).

Whilst there may be potentially conflicting opinions on the validity of prescriptions issued by prescribers registered within the EU, the position is clear that a prescription issued by a prescriber registered outside of the EU would not be legally valid in the UK.